510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K072599

General Information

Name and Address of Applicant
diaDexus, Inc.
343 Oyster Point Blvd.
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DEC 20 2007

Contact Person
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Date Prepared
September 13, 2007

Trade Name
PLAC® Test Reagent Kit
PLAC® Test Calibrator Kit
Lp-PLA_2 Control Kit

Common Name
Turbidimetric Immunoassay for the Quantitative Determination of Lp-PLA_2 (Lipoprotein-Associated Phospholipase A_2) in Human Plasma or Serum

Calibrators for use with Lp-PLA_2 Turbidimetric Immunoassay

Controls for use with Lp-PLA_2 Turbidimetric Immunoassay

Classification Name
TEST, SYSTEM, IMMUNOASSAY, LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (21 CFR 866.5600, Product Code NOE)

CALIBRATOR, SECONDARY (21 CFR 862.1150, Product Code JIT)

LIPOPROTEIN, LOW-DENSITY, ANTIGEN, ANTISERUM, CONTROL (21 CFR 866.5600, Product Code DFC)

Legally Marketed Device to which Equivalency is Claimed
PLAC® Test (k062234)

Description of Device

The diaDexus PLAC® Test assay consists of separately packaged reagents, calibrators and controls for the measurement of Lp-PLA_2 in serum or plasma on automated clinical chemistry analyzers.

- PLAC® Test Reagent Kit

  R1 Tris-based buffer solution

  R2 Suspension of latex microparticles coated with mouse monoclonal antibodies specific to Lp-PLA_2 (2C10 and 4B4).

- PLAC® Test Calibrator Kit

  Five level set of Lp-PLA_2 calibrators made with recombinant Lp-PLA_2 in a protein stabilizing buffer and used to calibrate the PLAC assay.

- Lp-PLA_2 Control Kit

  Two level set of Lp-PLA_2 controls made with recombinant Lp-PLA_2 in a protein stabilizing buffer and used for quality control of the PLAC assay.

The diaDexus PLAC® Test is based on turbidimetric immunoassay technology utilizing two Lp-PLA_2-specific monoclonal antibodies (2C10 and 4B4) coated to latex microparticles. A set of Lp-PLA_2 calibrators is used to plot a standard curve of absorbance (y-axis) versus Lp-PLA_2 concentration in ng/mL (x-axis) from which the Lp-PLA_2 concentration in the test sample can be determined. The concentration of Lp-PLA_2 in each sample and control is then interpolated from the standard curve using a spline curve fit with appropriate calibration curve fitting software. The kit expiration date and storage conditions are indicated on the package.

Characterization of Rare Reagents

Antigen

The antigen used in the diaDexus turbidimetric immunoassay PLAC® Test is purified recombinant Lp-PLA_2 (DDX-RA). Antigen preparations were characterized using SDS-polyacrylamide gels under reducing and non-reducing conditions and Western blot analysis using an anti-Lp-PLA_2 antibody, to demonstrate consistency with the molecular weight of the antigen reported in the literature.

Antibodies

The monoclonal anti-Lp-PLA_2 antibodies (2C10 and 4B4) used in the preparation of the coated microparticles were characterized for purity and reactivity in a series of procedures including Paragon gel electrophoresis, SDS-PAGE, size exclusion

chromatography, isotyping and enzyme immunoassay. These results demonstrated that the monoclonal antibodies bind to the Lp-PLA_2 antigen quantitatively and specifically.

Intended Use Statements

REAGENT KIT

The PLAC® Test Reagent Kit is a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma or serum on automated clinical chemistry analyzers, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis.

CALIBRATOR KIT

The PLAC® Test Calibrator Kit is intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA_2 by the PLAC® Test Reagent Kit.

CONTROL KIT

The Lp-PLA_2 Control Kit is intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC® Test Reagent Kit, a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2.

Comparison of Technological Characteristics

The chart below describes the similarities and differences between the device and the predicate, PLAC® Test ELISA kit.

	Predicate PLAC® Test k062234	**Device**
Intended Use	REAGENT KIT The diaDexus PLAC® Test is an enzyme immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma and serum, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis. (Calibrators included in kit.)	REAGENT KIT The PLAC® Test Reagent Kit is a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma or serum on automated clinical chemistry analyzers, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis. CALIBRATOR KIT The PLAC® Test Calibrator Kit is intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA_2 by the PLAC® Test Reagent Kit.
Intended Use	CONTROL KIT The Lp-PLA_2 Controls are intended for use with the diaDexus PLAC® Test, an enzyme immunoassay for the quantitative determination of Lp-PLA_2 in human plasma and serum. The Lp-PLA_2 Controls are intended as a Quality Control tool to monitor Lp-PLA_2 clinical laboratory results. Two levels of Controls are provided to monitor the performance within the clinical range of the assay.	CONTROL KIT The Lp-PLA_2 Control Kit is intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC® Test Reagent Kit, a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2.
Methodology	Microplate Enzyme immunoassay (ELISA)	Latex particle-enhanced turbidimetric immunoassay (particle agglutination)
Detection Method	Microplate spectrophotometer read at 450 nm	Automated clinical chemistry analyzers read at 570 nm
Analyte	Lp-PLA_2	Same
Sample	Serum, EDTA-plasma, heparin-plasma	Same
Reagent Components	Dual monoclonal antibody sandwich ELISA: • anti-Lp-PLA_2 mAb (2C10) coated stripwells • Wash Buffer • Enzyme Conjugate : anti-Lp-PLA_2 mAb (4B4)-HRP • TMB Substrate Solution • Stop Solution	Two-reagent system: • R1: Tris-based buffer solution • R2: Suspension of anti-Lp-PLA_2 (mAbs 2C10 and 4B4) coated latex beads

	Predicate PLAC® Test k062234	**Device**
Calibration	Six calibrators made with recombinant Lp-PLA_2 in a buffered protein matrix (included in ELISA kit)	Five calibrators made with recombinant Lp-PLA_2 in a buffered protein matrix (sold separately)
Calibration Levels	0, 50, 100, 250, 500, 1000 ng/mL	0, 50, 100, 250, 500 ng/mL
Quality Control	• 2 levels • Recombinant Lp-PLA_2 in a buffered protein matrix	Same
Risk to Patients	Minimal risk	Same
Laboratory Environment	Professional laboratory	Same

Performance Characteristics – Analytical

Sensitivity

The minimum detection limit is 4.0 ng/mL, as calculated by interpolation of the mean plus two standard deviations of 20 replicates of the 0 ng/mL Lp-PLA_2 calibrator from the standard curve.

Precision

Intra-assay precision (n=80) ranged from 1.6 %CV to 2.4 %CV throughout assay range (69 to 450 ng/mL).

Total precision (n=80) ranged from 1.8 %CV to 3.2 %CV throughout assay range (69 to 450 ng/mL).

Linearity/Assay Range

The average recovery in linearity experiments was 97%, demonstrating linearity of samples over a range of 96 to 472 ng/mL Lp-PLA_2.

Interfering Substances

No appreciable interference from the addition of the following substances was observed at the noted concentrations:

- Bilirubin 20 mg/dL
- Cholesterol 500 mg/dL
- Hemoglobin 10,000 mg/dL
- Triglycerides 3000 mg/dL
- Total Albumin* ~6500 mg/dL

* 2.5 g/dL albumin added to plasma pool of presumptively 4 g/dL albumin

Method Comparison

The turbidimetric immunoassay PLAC Test compared to the cleared PLAC Test (ELISA method) in a correlation study, and analyzed by linear regression, resulted in a correlation coefficient of $r = 0.95$, with a slope of 1.02.

Performance Characteristics – Clinical

No new clinical data were generated.

Conclusions

The latex-particle enhanced turbidimetric immunoassay PLAC Test has the same performance characteristics and clinical utility as the cleared enzyme immunoassay PLAC Test (k062234), and therefore is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

diaDexus, Inc.
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Executive Vice President of Diagnostics
343 Oyster Point Blvd.
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DEC 2 0 2007

Re: k072599
Trade/Device Name: PLAC® Test Reagent Kit
PLAC® Test Calibrator Kit
Lp-PLA_2 Control Kit
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: NOE, JIT, JJX
Dated: December 11, 2007
Received: December 12, 2007

Dear Dr. Wolfert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

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Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): K072599

Device Name: PLAC® Test Reagent Kit
PLAC® Test Calibrator Kit
Lp-PLA_2 Control Kit

Indication For Use:

The **PLAC® Test Reagent Kit** is a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma or serum on automated clinical chemistry analyzers, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis.

The **PLAC® Test Calibrator Kit** is intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA_2 by the PLAC® Test Reagent Kit.

The **Lp-PLA_2 Control Kit** is intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC® Test Reagent Kit, a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072599